IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	YOUNG, ET AL.	Confirmation No.	4470
Serial No.:	10/797,367	Art Unit:	1618
Filed:	10 March 2004	Examiner:	FUBARA, Blessing M.
For:	DRUG-ENHANCED ADHESION PREVENTION		
Docket No.:	ETH5095CIP	Customer No.:	25570

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

Responsive to the Final Rejection mailed January 8, 2010, and the Advisory Action mailed April 30, 2010 as to the above-referenced application, a Notice of Appeal having been filed on June 8, 2010, Appellants submit the following Appeal Brief.

1. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc., U.S. Route 22, Somerville, NJ, 08876-151, as evidenced by the assignment recorded at reel 015080, frame 0062.

2. RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

3. STATUS OF CLAIMS

Claims 28, 30-32, 34, 39 and 41 are finally rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement, which rejection is a subject of this appeal.

Claims 28, 30-32, 34, 39 and 41 are finally rejected under 35 U.S.C. §112, second paragraph as being indefinite, which rejection is a subject of this appeal.

Claims 28, 30-32 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14-19, 21-24 and 27-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat"). This rejection is not a subject of this appeal.

4. STATUS OF AMENDMENTS

The proposed amendment submitted on April 8, 2010 with Appellants' response to the final Office Action was not entered. However, since the proposed amendment was directed to matters of form only (i.e. a rearrangement of claim elements), Appellants submit that the unamended claims are suitable for this Appeal, and are set forth in the Claims Appendix (8) hereto.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

Under the provisions of 37 CFR 41.37(c)(1)(v), the following summary of claimed subject matter is made. The summary is in accordance with the rule

since the rule does not require any particular format for this section of the Appeal Brief. Note also that the commentary to the rules provides "[a]ppellant may include any other information of record which will aid the Board in considering the subject matter of each independent claim." 69 FR 49976, Comment 53, third column, August 12, 2004.

Claim 28 is directed to a composition suitable for local, non-systemic administration of a drug to a body and directly to tissue within a body cavity having been subjected to a surgical procedure, said composition consisting of Tranilast or an analog thereof (page 6, lines 15-19) selected from the group consisting of N-(2-Acetyl-4,5-dimethoxyphenyl)(4-((phenylamino)carbonylamino)-phenyl)formamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-2-(4-((phenylamino)-carbonylamino)phenyl)ethanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((phenylamino)carbonylamino)phenyl)prop-2-enamide, N-(2-Acetyl-4,5-di-methoxyphenyl)-3-(4-((phenylamino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-4-(4-((phenylamino)carbonyl amino)phenyl)butan-amide, N-(2-Acetyl-4,5-di-methoxyphenyl)-3-(4-(phenylcarbonylamino)carbonyl-amino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(2-phenyl-acetylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(phenoxycarbonyl-amino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(((2-nitro-phenyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(((3-nitrophenyl)amino)carbonylamino)-phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-nitrophenyl)-amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((2-aminophenyl)amino)-carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((3-aminophenyl)amino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-aminophenyl)amino)-carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-fluorophenyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-di-methoxyphenyl)-3-(4-(((4-acetyl-phenyl)amino)carbonylamino)phenyl)propan-amide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-methylphenyl)amino)-

carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-methoxyphenyl)amino)carbonylamino)-phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((3,4,5-trimethoxyphenyl)amino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(((4-pyridyl)amino)-carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((benzylamino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-((butylamino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((cyclohexylamino)carbonylamino)phenyl)propanamide, and a potassium, sodium, calcium and magnesium salt of Tranilast (page 9, line 17 to page 11, line 11), in an amount effective to inhibit formation of post-operative adhesions upon local, non-systemic administration of said composition to said tissue (page 6, line 27 to page 7, line 3), a biodegradable polymer in a form selected from the group consisting of film, foam, fibers and filaments (page 17, lines 12-18), suitable for local, non-systemic administration of said Tranilast or analog thereof, and optionally a therapeutic agent in an amount effective to provide the therapeutic effect intended by administration of said therapeutic agent (page 20, line 15 to page 22, line 24).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement.

II. Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, second paragraph as being indefinite.

7. ARGUMENT

The Rejections

I. Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, first paragraph for failing to comply with the written description requirement.

a. Separate argument of claim 28

At page 2 of the outstanding Office Action, the Examiner states:

> The recitation that [the] delivery vehicle consists of tranilast was not envisioned...It is suggested that applicant direct the examiner to section of the specification as originally filed that supports the claimed composition consisting of tranilast and polymer and an optional therapeutic agent.

Appellants direct the Board's attention to the following paragraphs, reproduced here in part and highlighted for the Board's convenience.

> A large variety of alternative sustained release delivery vehicles for administering Tranilast or analogs thereof also are contemplated as within the scope of the present invention when containing therapeutically effective amounts of Tranilast. Suitable delivery vehicles include, but are not limited to, microcapsules or microspheres; liposomes and other lipid-based release systems; absorbable and/or biodegradable mechanical barriers; polymeric delivery materials such as, but not limited to, polyethylene oxide/polypropylene oxide block copolymers (i.e., poloxamers), poly(orthoester)s, poly(vinyl alcohol)s, poly(anhydride)s, poly(methacrylate)s, poly(methacryladmide)s, anionic carbohydrate polymers, poly(hydroxybutyric acid)s, and polyacetals. (Page 13, lines 13 et seq.)
>
> Moreover, alternative delivery systems based on biodegradable polymers and that are suitable for use in accordance with the present invention, for example, fibers, films, foams, or

> filaments comprising the active agents, also are contemplated as being within the scope of the present invention when containing effective amounts of Tranilast or analogs thereof. (Page 17, lines 12-18)

Accordingly, Appellants submit that a composition of Tranilast and a biodegradable polymer in the form of fibers, films, foams or filaments is sufficiently supported in the present specification.

Support for the therapeutic agents can be found at page 20, lines 15 et seq.

Clearly the application when considered as a whole, supports the present claim language and meets the written description requirement of 35 U.S.C. §112. Reversal of the rejection is requested.

b. Separate argument of claims 30-32, 34, 39 and 41

Solely for the purpose of this appeal, claims 30-32, 34, 39 and 41 will not be separately agued and will stand or fall with claim 28.

Reversal of the rejection is courteously solicited.

II. Claims 28, 30-32, 34, 39 and 41 are rejected under 35 U.S.C. §112, second paragraph as being indefinite.

a. Separate argument of claim 28

The Examiner indicates that the term "therapeutic agent" is indefinite, since in her opinion Tranilast is also a therapeutic agent and "it is unclear if the optional therapeutic agent excludes tranilast" (Office Action of January 8, 2010, page 3, paragraph 9).

Appellants respectfully submit that one skilled in the art would have had no confusion as to whether Tranilast was included as an additional therapeutic agent, since Tranilast is recited prominently in the base claim as a required component.

Appellants respectfully submit that the skilled artisan would look to the specification for a recitation of suitable, optional therapeutic agents and find "Tranilast" absent. Also, since the additional "therapeutic agents" are optional, the issue is essentially moot.

Reversal of the rejection is courteously solicited.

b. Separate argument of claims 30-32, 34, 39 and 41

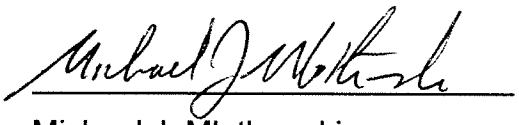
Solely for the purpose of this appeal, claims 30-32, 34, 39 and 41 will not be separately agued and will stand or fall with claim 28.

Reversal of the rejection is courteously solicited.

The Board of Appeals is respectfully requested to remand this application to the Examiner with a direction to allow the claims.

Respectfully submitted,

Date: August 9, 2010



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8. CLAIMS APPENDIX

28. A composition suitable for local, non-systemic administration of a drug to a body and directly to tissue within a body cavity having been subjected to a surgical procedure, said composition consisting of Tranilast or an analog thereof selected from the group consisting of N-(2-Acetyl-4,5-dimethoxyphenyl)(4-((phenylamino)carbonylamino)phenyl)formamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-2-(4-((phenylamino)carbonylamino)phenyl)ethanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((phenyl-amino)carbonylamino)phenyl)prop-2-enamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-((phenylamino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-4-(4-((phenylamino)carbonyl amino)phenyl)butanamide, N-(2-Acetyl-4,5-di-methoxyphenyl)-3-(4-(phenyl-carbonylamino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(2-phenylacetylamino)-phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(phenoxycarbonyl-amino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((2-nitro-phenyl)amino)carbonylamino)-phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(((3-nitrophenyl)-amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-nitrophenyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((2-aminophenyl)amino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((3-aminophenyl)amino)-carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-aminophenyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-fluorophenyl)amino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-acetyl-phenyl)amino)-carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-methylphenyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((4-methoxyphenyl)amino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-(((3,4,5-trimethoxyphenyl)-amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxy-phenyl)-3-(4-(((4-pyridyl)amino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-

dimethoxyphenyl)-3-(4-((benzylamino)carbonylamino)phenyl)propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((butylamino)carbonylamino)phenyl)-propanamide, N-(2-Acetyl-4,5-dimethoxyphenyl)-3-(4-((cyclohexylamino)-carbonylamino)phenyl)propanamide, and a potassium, sodium, calcium and magnesium salt of Tranilast, in an amount effective to inhibit formation of post-operative adhesions upon local, non-systemic administration of said composition to said tissue, a biodegradable polymer in a form selected from the group consisting of film, foam, fibers and filaments, suitable for local, non-systemic administration of said Tranilast or analog thereof, and optionally a therapeutic agent in an amount effective to provide the therapeutic effect intended by administration of said therapeutic agent.

30. The composition of claim 28 wherein said biodegradable polymer is selected from the group consisting of poloxamers, poly(orthoester)s, poly(vinyl alcohol)s, poly(anhydride)s, poly(methacrylate)s, poly(methacrylamide)s, anionic carbohydrate polymers, poly(hydroxybutyric acid)s, polyacetals, poly(1-lactide), poly(dl-lactide), poly(dl-lactide-co-glycolide)s, poly(1-lactide-co-glycolide)s, poly(e-caprolactone), polyglycolide, poly(p-dioxanone)s, poly(trimethylene carbonate), poly(alkylene diglycolate)s, poly(oxaester)s, poly(oxaamide)s and glyceride polymers.

31. The composition of claim 28 wherein said composition provides for single dose administration of said Tranilast or analog thereof.

32. The composition of claim 28 wherein said composition provides for sustained release of said Tranilast or analog thereof.

34. The composition of claim 28 comprising from about 0.01 milligram Tranilast or analog thereof per kilogram of the body to about 3,000 milligram Tranilast or analog thereof per kilogram of the body.

39. The composition of claim 28 wherein said biodegradable polymer is selected from the group consisting of hyaluronic acids, collagens, pluronics, chitin, chitosans, dextrans, glucoses, carbohydrates, gelatins, glycosaminoglycans, aliginates, starches and polypeptides.

41. The composition of claim 28 wherein said therapeutic agent is present and is selected from the group consisting of an anti-platelet, an anti-fibrotic, an anti-inflammatory, an anti-proliferative and an agent that inhibits collagen synthesis.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.